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5. DISCUSSION OF SAFETY AND EFFECTIVENESS

A. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Model No. /Names:	MedX 1100 Console and MedX LCT 100 & Duolight 100 & 500 Accessories MedX LCS 100 Portable Laser
Classification:	Lamp Infrared, Heating Category ILY Physical Medicine Device, 21 CFR 890.5500 (Class II)
Predicate Devices:	K020017 MedX 1000 Series Console & LED Accessories – MedX MCT 600 and MedX MCT 150
Contact Person:	Phil Passy President and CEO MedX Health Inc. 905 826-0766

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description of the Device

The MedX 1100 Console powers three different accessories the MedX LCT 100 (785 nm) and Duolight 100 (785 nm) & 500 Accessories. All therapeutic heating accessories are indication for use within the heating category, ILY, as applied for in this submission. The low level laser accessories use 785 nm GaAlAs (gallium-aluminum-arsenide) infrared lasers diodes indicated for use where heat is indicated for topical heating for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, and minor pain and stiffness associated with arthritis.

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Technological Characteristics Summary

The technological characteristics are based on the predicate device – K020017.

Discussion of Non-Clinical and Clinical Data

No research was conducted for this specific 510(k) submittal.

Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for the MedX 1100 Console and infra red heating accessories and the MedX LCS 100 Portable Laser indicates that they meet design and performance functional requirements. The proposed device meets the requirements of international and US medical electrical equipment standards for safety, and key performance and safety requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2003

Ms. Anita Saltmarche
Vice President Clinical and Scientific Affairs
MedX Electronics, Inc.
3535 Laird Road, Unit 2
Mississauga, Ontario
Canada L5L 5Y7

Re: K032231
Trade/Device Name: MedX 1100 Console & MedX LCT 100 (785 nm) and
Duolight 100 (785 nm) & 500 Accessories
MedX LCS 100 Portable Laser (785 nm)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: July 17, 2003
Received: July 31, 2003

Dear Ms. Saltmarche:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Number: K032231

Device Names: **MedX 1100 Console & MedX LCT 100 (785 nm) and Duolight 100 (785 nm) & 500 Accessories**
MedX LCS 100 Portable Laser (785 nm)

INDICATION FOR USE

Indication for Use

The MedX 1100 Console and MedX LCT 100 (785 nm) and Duolight 100 (785 nm) & 500 Accessories are an infrared lamp system, as per 21 CFR 890.5500. The energy emitted provides topical heating for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.

The MedX LCS 100 Portable Laser (785 nm) is an infrared lamp, as per 21 CFR 890.5500. The energy emitted provides topical heating for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-counter Use _____
(Optional Format 1-2-96)

(Division Sign-off)
Division of General Restorative Devices
510(k) Number: K032231

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032231